#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Assistant Com	missioner for Patents		
		Name (Print)	(Signature)
		I hereby certify that of deposited this paper and that it was addre- Commissioner of Pat	Label No
For: NEST	ED STENT	Dated: May 1	6, 2000
Filed: March	17, 1999	Docket:	498-67 CON 2
Serial No.:	09/271,304	Group Art Un	nit: 3738
Applicant(s):	Rudnick et al.	Examiner:	D. Isabella

# DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME A PATENT UNDER 37 C.F.R. § 1.131

Sir:

Washington, DC 20231

- We, James J. Rudnick, and Dominik M. Wiktor, both citizens of the United States, residing respectively at 11 Clearwater Court, Mahwah, NJ 07430 and 6441 3<sup>rd</sup> Palm Point, Saint Petersburg, Florida 33706-2123, are joint inventors of the above-identified application.
- 2. At the time of the invention thereof we were working for Meadox Medicals, Inc., assignee of the present application. With respect to the inventor Rudnick, I was an employee of Meadox Medicals, Inc. and with respect to inventor Wiktor, I was a consult

for Meadox Medicals, Inc. We submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to April 1, 1994, i.e. the effective date of U.S. Patent No. 5,876,432, Lau et al. (hereinafter the '432 patent), which was cited by the Examiner in an Office Action mailed December 29, 1999.

- 3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention was completed in the United States before April 1, 1994 which is a date earlier than the U.S. filing date of the '432 patent. Completion of the invention prior to April 1, 1994, is shown by conception and actual reduction to practice of the invention as evidenced by construction and testing of a nested stent.
- 4. To establish conception and reduction to practice, i.e. completion of the invention at a date prior to April 1, 1994, the following documents being submitted as evidence:
  - a. A Meadox Medicals, Inc. invention disclosure (Exhibit A) bearing dates signed by the inventors and dates signed by witnesses prior to April 1, 1994, the filing date of the '432 patent. (The dates have been redacted to prevent their unnecessary disclosure.) That invention disclosure describes the nested stent of the present invention where the benefits of the device are described as follows: "all of the above being accomplished by providing maximum monofiliment wire density in a minimum volume of space by proper nesting of convolutions of formed wire over a mandrel." In an attachment to that invention disclosure, a drawing of the nested

stent is shown. The drawing shown in the attachment to the invention disclosure is substantially similar to the drawings shown in Figures 2 and 8 of the present application. This invention disclosure evidences conception of the invention prior to April 1, 1994.

- b. A confidential report entitled "Stent Analysis Summary" (Exhibit B) prepared by Product Genesis Inc., an engineering and design firm, which was retained by assignee, Meadox Medicals, Inc., to conduct an engineering analysis of the nested stent which is the subject of the claims of the present application. That report bearing a final issue date prior to April 1, 1994 (also redacted), includes a drawing labeled Figure 2-2 "Stacked Packing Geometry" showing a drawing of the nested stent of the present invention. Further and as evidence of completion of the invention, the report of Exhibit B includes photographs at Figures 4-4 through 4-7 showing the constructed nested stent of the present invention. Also as an attachment to this report are two spreadsheets showing design variables for construction of the nested stent of the present invention. Certain of these design variables have been included in the present application, being incorporated into Table 1.
- 5. The materials submitted herewith establish that the invention was completed, i.e. conceived and reduced to practice at a date prior to April 1, 1994, the filing date of the '432 patent.

- 6. This declaration is submitted in a response to a first Office Action issued by the Examiner and is therefore believed to be timely filed.
- 7. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

DATED: MAY 17, 2000	James J. Rodnick
DATED:	Dominik Wiktor

MEADOX L DICALS, INC. INVENTION UID	CLL JHE
1. GIVE TITLE OF YOUR IDEA:	-
HI-STRENGTH HI-WIRE DENSITY INTRAVASCULAR	EXPANDABLE STENT
DESCRIBE YOUR IDEA IN DETAIL AND INCLUDE SKETCH AND FORMUL Intraluminal Stent characterized by its ability to compressive forces, also to discourage encroachment between wires after deployment, yet maintain full above being accomplished by providing maximum more in a minimum volume and space. by proper nesting wire over a mandrel	to resist external ent of cell ingrowth flexibility; all of the nofilament wire density
STATE ADVANTAGES OVER EXISTING PRODUCTS OR METHODS: Presently used and known Stents, specifically as by Wiktor, although similar in design and basic of high strength nor tight wire nesting as the Sten	construction do not provide
4. ATTACH AND IDENTIFY COPIES OF ALL KNOWN REFERENCES, DRAWII ARTICLES, TEXTBOOKS, ETC. (Note: All entries made in Laboratory Notabooks, m by suthor, recipient, date, project number, book number, and page number, if applicable.  First memo to J.Rudnick , subseque Dominik M. Wiktor developed thus reduced a them model; several models constructed and expanded o samples constructed and together with a memo sen	emoranda comespondence or similar documentation  Concept Meeting,  nt meeting at MEADOX  pretical idea to a a working  ver a balloon, additional
5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT:  James J.Rudni	
SIGNATURE(S) OF INVENTOR(S) DATE PRINT NAME OF INVENTOR(S)	HOME ADDRESS
Donning M. Wiktor	4 Culin Drive Cranford, NJ 07
James Hudrudt James Rudnick	74 Moore Ave, Waldwick,NJ 07463
<i>( )</i>	
WITNESSED AND UNDERSTOOD BY:  Anthony M. Spadaro Printer Patent Review:	nt Name Cate:
Yes No	Date:
Yes No Vice	President Date:
EXECUTIVE COMMITTEE FIEVIEW:	
Approved for	President Date:
	President Date:
Comments:	

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James Kuli James J. RUD. DOMINIK M.	DATE RETOR	7-4 1	Jacker - DATE

EACH PAGE MUST BE SIGNED, WITNESSED, AND DATED.



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300 dent Street Suite 200 Cambridge, MA 02141 617 661 3552 FAX 617 661 0126

## Stent Analysis Summary

FINAL ISSUE

For: Meadox/SurgiMed 112 Bauer Drive Oakland, NJ 07436 1-800-221-1542

By: Product Genesis, Inc. 300 Bent Street, Suite 200 Cambridge, MA 02141 617-661-3552

### CONFIDENTIAL

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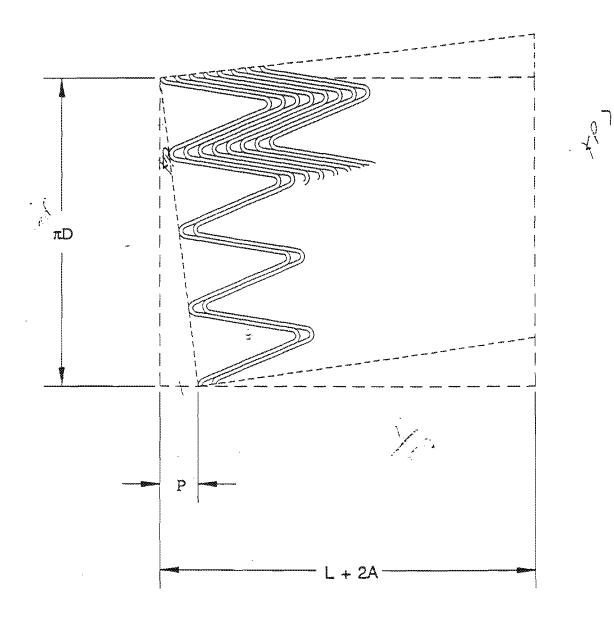
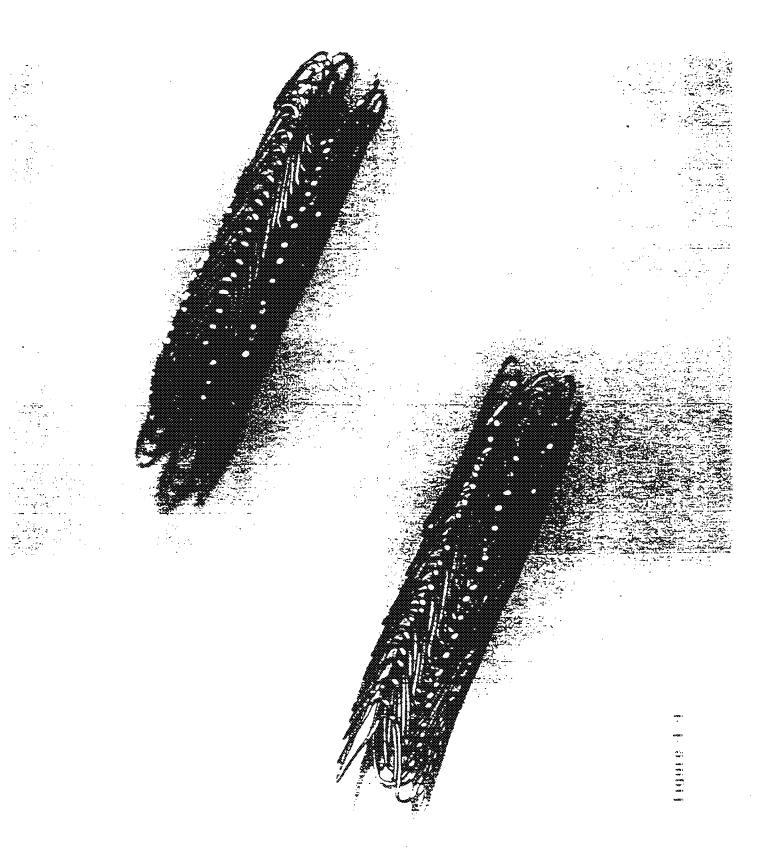
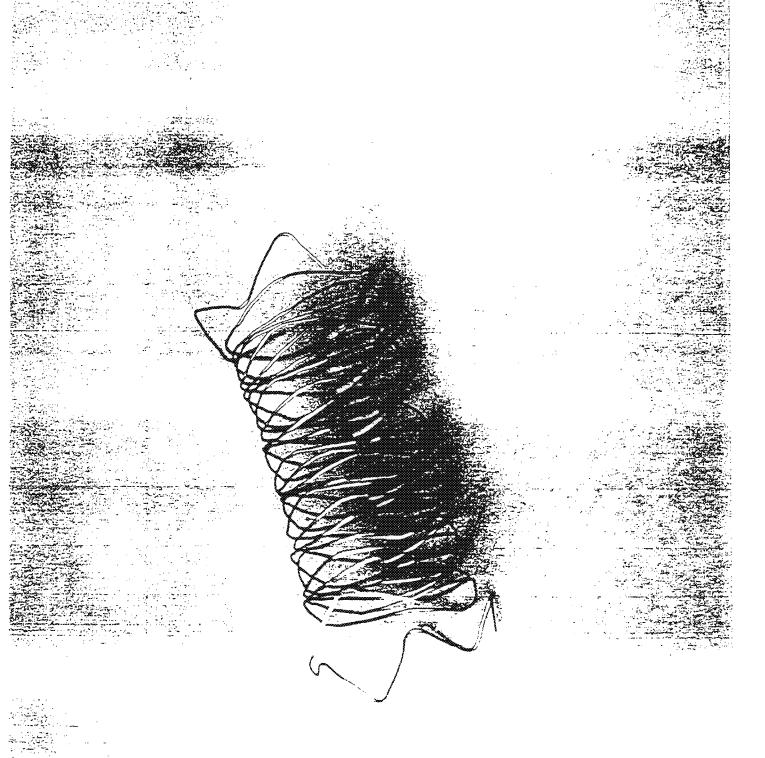


Figure 2-2: Stacked Packing Geometry







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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Rudnick et al.	Examiner: D. Isabella
Serial No.: 09/271,304	Group Art Unit: 3738
Filed: March 17, 1999	Docket: 498-67 CON 2
For: NESTED STENT	Dated: May 16, 2000
	DateLabel NoI hereby certify that on the date indicated above I deposited this paper or fee with the U.S. Postal Service and that it was addressed for delivery to the Assistant Commissioner of Patents, Washington, D.C. 20231 by "EXPRESS MAIL POST OFFICE to ADDRESSEE " service
	Name (Print) (Signature)
Assistant Commissioner for Patents	

# DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME A PATENT UNDER 37 C.F.R. § 1.131

Sir:

Washington, DC 20231

- We, James J. Rudnick, and Dominik M. Wiktor, both citizens of the United States, residing respectively at 11 Clearwater Court, Mahwah, NJ 07430 and 6441 3<sup>rd</sup> Palm Point, Saint Petersburg, Florida 33706-2123, are joint inventors of the above-identified application.
- 2. At the time of the invention thereof we were working for Meadox Medicals, Inc., assignee of the present application. With respect to the inventor Rudnick, I was an employee of Meadox Medicals, Inc. and with respect to inventor Wiktor, I was a consult

for Meadox Medicals, Inc. We submit this declaration to establish completion of the invention set forth in this application in the United States at a date prior to April 1, 1994, i.e. the effective date of U.S. Patent No. 5,876,432, Lau et al. (hereinafter the '432 patent), which was cited by the Examiner in an Office Action mailed December 29, 1999.

- 3. From the documents submitted herewith and as set forth hereinbelow, it can be seen that the invention was completed in the United States before April 1, 1994 which is a date earlier than the U.S. filing date of the '432 patent. Completion of the invention prior to April 1, 1994, is shown by conception and actual reduction to practice of the invention as evidenced by construction and testing of a nested stent.
- 4. To establish conception and reduction to practice, i.e. completion of the invention at a date prior to April 1, 1994, the following documents being submitted as evidence:
  - a. A Meadox Medicals, Inc. invention disclosure (Exhibit A) bearing dates signed by the inventors and dates signed by witnesses prior to April 1, 1994, the filing date of the '432 patent. (The dates have been redacted to prevent their unnecessary disclosure.) That invention disclosure describes the nested stent of the present invention where the benefits of the device are described as follows: "all of the above being accomplished by providing maximum monofiliment wire density in a minimum volume of space by proper nesting of convolutions of formed wire over a mandrel." In an attachment to that invention disclosure, a drawing of the nested

stent is shown. The drawing shown in the attachment to the invention disclosure is substantially similar to the drawings shown in Figures 2 and 8 of the present application. This invention disclosure evidences conception of the invention prior to April 1, 1994.

- b. A confidential report entitled "Stent Analysis Summary" (Exhibit B) prepared by Product Genesis Inc., an engineering and design firm, which was retained by assignee, Meadox Medicals, Inc., to conduct an engineering analysis of the nested stent which is the subject of the claims of the present application. That report bearing a final issue date prior to April 1, 1994 (also redacted), includes a drawing labeled Figure 2-2 "Stacked Packing Geometry" showing a drawing of the nested stent of the present invention. Further and as evidence of completion of the invention, the report of Exhibit B includes photographs at Figures 4-4 through 4-7 showing the constructed nested stent of the present invention. Also as an attachment to this report are two spreadsheets showing design variables for construction of the nested stent of the present invention. Certain of these design variables have been included in the present application, being incorporated into
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DATED:		
		James J. Rudnick
DATED:	MAT 18 2000	Dommer brang
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MEADOX I. DICALS, INC. INVENTION DISCLO JAE

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#### ATTACH NT TO INVENTION DISCLOSURE FORM

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300 Bent Street Suite 200 Cambridge, MA 02141 617 661 3552 FAX 617 661 0126

## Stent Analysis Summary

FINAL ISSUE

For: Meadox/SurgiMed 112 Bauer Drive Oakland, NJ 07436 1-800-221-1542

By: Product Genesis, Inc. 300 Bent Street, Suite 200 Cambridge, MA 02141 617-661-3552

### CONFIDENTIAL

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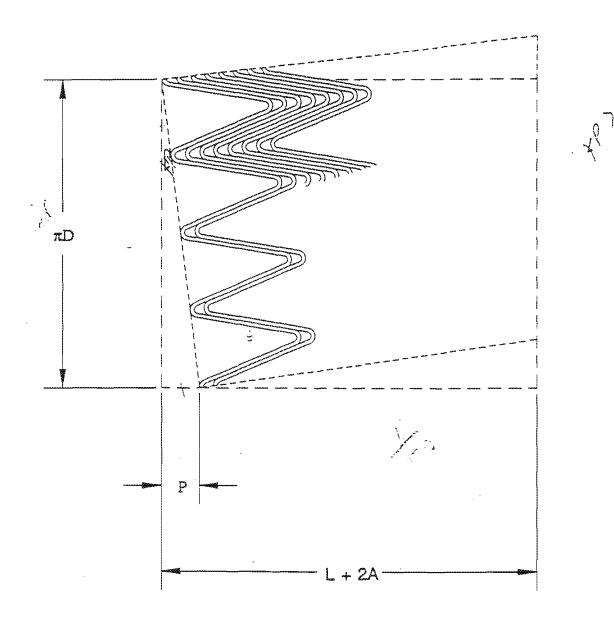
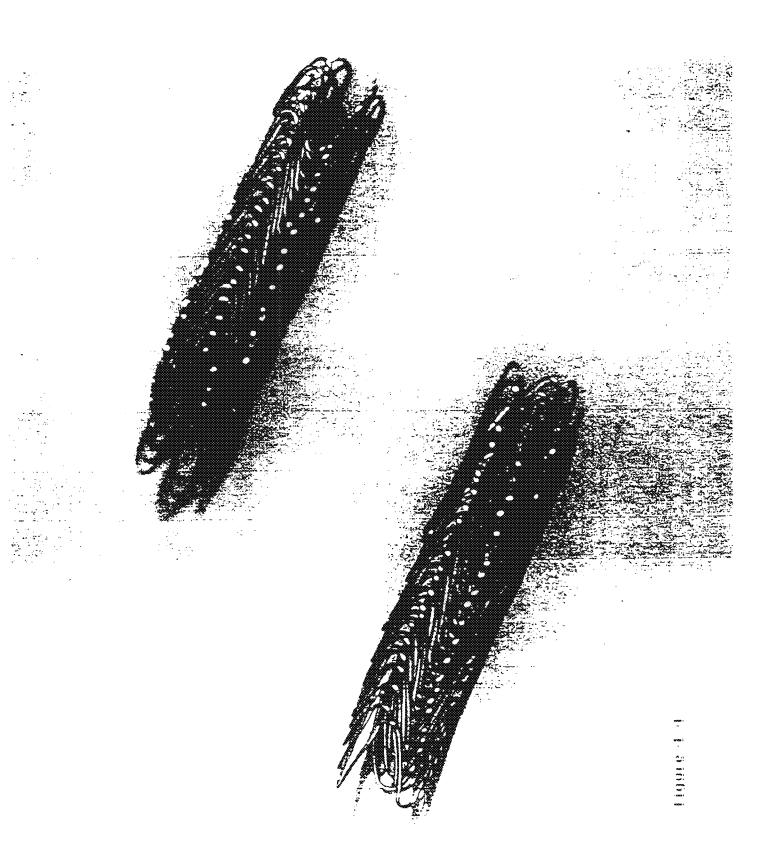
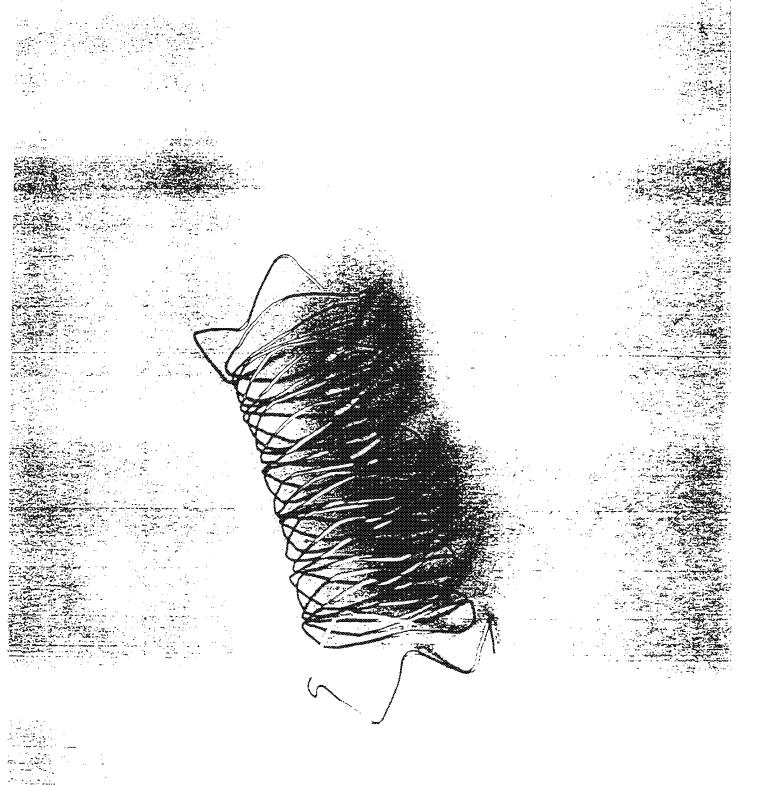


Figure 2-2: Stacked Packing Geometry





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